

REMARKS

With this response, Claims 1 and 23 have been amended, and Claims 14-17 have been canceled without prejudice or disclaimer. No claims have been added. As such, Claims 1-9, 11-13, 18-19, 22 and 23 are pending. No new matter enters by way of the present amendment. As such, entry of the amendment and reconsideration of the application as amended is respectfully requested.

I. Rejections under 35 U.S.C. § 112, First Paragraph

Claims 14-17 stand rejected under 35 U.S.C. § 112, First Paragraph as allegedly failing to comply with the written description requirement for containing new matter. While not agreeing with the rejection, solely to facilitate prosecution, Applicants have canceled the claims without prejudice or disclaimer to the underlying subject matter. As such, this rejection is now moot.

II. Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 11-19, 22, and 23 stand rejected under 35 U.S.C. § 112, Second Paragraph as allegedly being indefinite. Applicants respectfully traverse for at least the reasons which follow.

The Examiner objects to the claim scope in that Claim 1 recites “5-aminolevulenic acid and derivatives thereof”, while dependent claims thereof recite porphyrins, etc. wherein, according to the Examiner, the “porphyrins, derivatives thereof and proporphyrins are seen as derivatives because they are formed endogenously after application of δ ALA.” Office Action mailed December 9, 2010 at page 5. While not agreeing with the rejection, Claim 1 has been amended to recite “5-aminolevulenic acid and analogs thereof” to clarify a structural derivative of the parent compound rather than a compound in a synthetic chain. As such, it is submitted that those of skill in the art would understand the scope of the negative proviso in Claim 1 vis-à-vis the dependent claims, and would be able to ascertain with a reasonable degree of precision and particularity the scope of the claims such that there is no conflict between Claim 1 and the dependent claims. *Ex Parte Wu*, 10 USPQ 2d, 2031, 2033 (B.P.A.I. 1989) (citing *In re Moore*, 439 F.2d 1232 (C.C.P.A. 1971)). As such, withdrawal of this rejection is respectfully requested.

III. Rejections under 35 U.S.C. § 103

Claims 1-9, 11-13, 18, 19, 22 and 23 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over QLT Inc. WO 03/039597 A1 (hereinafter “QLT”) in view of Kalka et al J Am Acad Dermatol Mar 2000 (hereinafter “Kalka”) as allegedly being obvious. Applicants respectfully traverse for at least the reasons which follow.

The present independent claims are directed to methods for treating hyperactive sebaceous gland disorders, other than acne, in a subject in need thereof, the method comprising topically applying a photosensitizer composition to skin tissue of said subject exhibiting symptoms of a hyperactive sebaceous gland disorder and exposing the tissues of said subject to light energy. As acknowledged by the Examiner, QLT is completely silent with regard to methods for treating hyperactive sebaceous gland disorders, but rather teaches the treatment of other skin conditions and disorders. To remedy this deficiency, the Examiner points to alleged teachings of Kalka and asserts that it would have been obvious to those skilled in the art to employ methods of treating hyperactive sebaceous gland disorders “motivated by the teaching of Kalka and QLT Inc. that teach both psoriasis and seborrhea are well known to be treated with porphyrins and light energy.” Office Action mailed December 9, 2010 at page 7. Applicants respectfully traverse.

In this regard, it is submitted that Kalka does not in fact teach the treatment of hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof and exposing the tissue of the subject to light energy, as required by the claims. Rather, Kalka mentions that “lipophilic propionibacteria has been utilized for photodynamic destruction of these micro-organisms for the management of acne vulgaris. Repeated illumination with blue light at cumulative dose of 325 J/cm² resulted in marked reduction of both acne and seborrhea. [. . .] The possible value of topical PDT for benign inflammatory skin disease need further exploration.” Kalka, page 403. Such disclosure does not reference the topical application of a photosensitizer composition to skin tissue of subject exhibiting symptoms of a hyperactive sebaceous gland disorder. Rather, it merely references the destruction of lipophilic propionibacteria for management of acne vulgaris via use

of blue light, and a resultant reduction in both acne and seborrhea. Kalka then suggests the possible value of PDT for benign inflammatory skin diseases and suggests further exploration.

At a minimum, in order to arrive at the presently claimed invention, one of skill would need to modify the teachings of QLT and Kalka so as to specifically provide a method with an intent to treat hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. Again, the present claims require such a method, including topical application of a photosensitizer composition to skin tissue of a subject. The Federal Circuit has directly addressed this issue of claim interpretation, and held that “the claims’ recitation of a patient or a human ‘in need’ gives life and meaning to the preamble’s statement of purpose. [. . .] The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed.” *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (*citations omitted*).

In interpreting a claim directed to a “method of treating macrocytic-megaloblastic anemia in... a human in need thereof,” the Federal Circuit held that the claim preamble is a limiting “statement of intentional purpose.” *Jansen v. Rexall Sundown*, 342 F.3d at 1333. The Court explained that “administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method.” “[T]he combination of folic acid and vitamin B[12] must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.” *Jansen v. Rexall Sundown*, 342 F.3d at 1334.

In accordance with proper claim interpretation, the present claims require a method with an intent to treat hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. The mere disclosure in Kalka of destruction of lipophilic prionibacteria for management of acne vulgaris, the passing reference to reduction in both acne and seborrhea, and the express suggestion of possible value of PDT for benign inflammatory skin diseases and of further exploration is just that --- an invitation for further experimentation with no reasonable expectation of success concerning the specific intent of the presently claimed invention.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. There must also be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Moreover, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning **with some rational underpinning** to support the legal conclusion of obviousness.” *KSR Int’l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added).

As mentioned above, nothing in QLT or Kalka teaches or suggests a method with an intent to treat hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof. Absent a suggestion of such a method, one of skill in the art would simply find no motivation to perform a method as recited in the present claims for the specific intended purpose of treating hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to a subject in need thereof. Further, there is no motivation to specifically modify the teaching of Kalka so as to arrive at the specifically claimed methods with any reasonable expectation of success. For at least these reasons, one of skill in the art would not look to modify the teachings of QLT alone or in view of Kalka so as to arrive at the presently claimed invention. Withdrawal of this rejection is therefore respectfully requested.

The dependent claims are believed to be patentable for at least the reasons discussed above. In addition, each of the claims further recite specific parameters with regard to the treatment regimen and composition and are separately patentable for at least these reasons.

For at least the foregoing reasons, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

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